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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,307	10/26/2001	Michael R.S. Hill	P-8969.00	2140
27581	7590	04/21/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/039,307

Applicant(s)

HILL ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/21/05(Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response***

1. The Applicant amended the independent claims, hence a new grounds of rejection has been established with respect to claims 1-40.

### ***Claim Rejections - 35 USC § 102***

2. Claims 1, 2, 4-13, 15-18, 20-34 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (US 5199428). Obel et al. disclose an implantable electrical nerve stimulator/ pacemaker, the nerves being stimulated in the region of the thoracic vertebra T2 and the stimulation coordinated with the heart to provide resynchronization therapy (abstract; col. 1 @ 15-24; col. 3 @ 8-28 & 42-45; col. 3 @ 62 – col. 4 @ 26; col. 5 @ 25-64). Anti-tachycardia pacing may be incorporated (col. 9 @ 53 – col. 10 @ 2). Cardiac disease associated with the loss of vagal tone are treated automatically using neural stimulation (col. 1 @ 9-13; col. 5 @ 3-18).

### ***Claim Rejections - 35 USC § 103***

3. Claims 3, 19, and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Adams (US 57992187). As discussed in paragraph 2 of this action, Obel et al. disclose the claimed invention except for the driver circuit delivering high-voltage stimulation (claim 39), and the electrode located external to the patient's body (claims 3 and 19).

As to delivering high voltage stimulation, Adams teaches cardiac arrhythmia treatment using cardioversion/ defibrillation shock therapy for the purpose of converting dysrhythmia to normal sinus rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used high voltage stimulation in the Obel et al. system in order to offer a proven alternate treatment for arrhythmias so the dysrhythmia is effectively treated before the patient suffers any ill effects from the dysrhythmia (col. 3 @ 1-8).

As to the electrode being located external to the patient's body, Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the Obel et al. system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension and anxiety is controlled (abstract; col. 2 @ 48-55; col. 3 @ 1-8 & 45-48; col. 7 @ 11-24). It is noted both electrical and electromagnetic pain suppression systems are well known in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

4. Claims 14, 35 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Sweeney et al. (US 6272377). As discussed in paragraph 2 of this action, Obel et al. disclose the claimed invention except for the electrode being located on

Art Unit: 3762

an intrinsic cardiac ganglia (claims 14, 35) and providing a drug delivery device with agent (claim 40).

Sweeney et al. teach arrhythmia treatment using drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) for the purpose of preventing the development of an arrhythmia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used drug delivery and/ or nerve stimulation using as electrode on the fat pad over the atrioventricular node (an intrinsic cardiac ganglia) in the Obel et al. system in order to provide alternate proven means to prevent or reduce the consequences of the arrhythmia (abstract; col. 4 @ 61 – col. 5 @ 5; col. 8 @ 49-55).

### *Drawings*

5. The drawings stand objected to because:
- In figure 2, the “Pacing/ High-Voltage Stimulation” box does not have a reference numeral, and
  - In figure 5, the reference numeral “500” is used twice to refer to two different steps.

### *Specification*

6. The specification stands objected to because:
- The Serial Numbers, Patent number needed to be supplied on pages 1 and 9 of the specification,
  - On page 10, line s 28 and 31, the reference numeral “213” is used twice to define two different elements, and
  - One page 14, line 1, reference numeral “(504)” is not found in figure 5.

*Statutory Basis*

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Conclusion*

**THIS ACTION IS MADE FINAL.** The Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frances P. Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on (571) 272-4955. The telephone number for facsimiles for regular communication and After Final communications is (703) 872-9306.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*4/10/05*

*Angela D. Sykes*

**ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700**